



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/132,593	08/11/1998	ASGEIR SAEBO	21440/9015	9659

23535 7590 07/24/2003
MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER

WANG, SHENGJUN

ART UNIT PAPER NUMBER

1617

DATE MAILED: 07/24/2003

41

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/132,593

Applicant(s)

SAEBO ET AL.

Examiner

Shengjun Wang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 6, 2003 has been entered.

Receipt of applicant's remarks submitted May 6, 2003 is acknowledged.

Claim Objections

2. Claim 3 is objected to because of the following informalities: claim 3 recites "t10, c12-octadecanoic" in line 4, it appears to be a typographic error for "t10, c12-octadecadienoic".

Appropriate correction is required.

Claim Rejections 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US 5,554,646 of record) in view of applicants' disclosure at page 11, line 13-25 in the specification, Cain et al. (WO 97/18320, IDS April 13, 2000), and Chin et al. (IDS, November 23, 1999), in further view of Baltes et al. (US Patent 3,162,658, IDS May 23, 1999).

Cook'646 teaches an active form conjugated linoleic acid, i.e., 10,12-octadecadienoic acid and 9,11-octadecadienoic acid, which including ester, salt and free acid of conjugated linoleic

Art Unit: 1617

acid. See. Particularly, column 1-lines 65-67, column 2, line 1 and column 4, lines 1-9. The conjugated linoleic acid may be obtained through isomerization of safflower oil. See column 2, lines 12-45. Cook et al. further teach a food product comprising the said active form of conjugated linoleic acid. See, particularly, column 1, lines 39-60 and examples 1-4. The feeding may also comprising phosphatides. See, column 5, line 47. '646 also teach a safe and effective method for reducing body fat in animal by administering the said food product. See, particularly, the abstract. C9, t11- and t10, c12- isomer are predominantly major isomer of the conjugated linoleic acid active form of Cook'646. See, particularly, column 4, lines 50-55.

Cook et al. do not teach expressly the conjugated linoleic acid active form further comprising the regio isomers 8,10- and an 11,13- octadecadienoic acid derivative, or specify the particular amounts of each 9, 11 and 10, 12 isomers of octadecadienoic acids, or the amount of phosphatides.

However, since the preferred amounts of the regio isomers 8,10- and an 11,13- octadecadienoic acid derivative in the claimed invention are limited to less than 2 percent, this amount includes zero percent of the regio isomers as disclosed by Cook. Thus, Cook' teachings meet this limitation. Chin et al. each that it is known that c9; t11- conjugated linoleic acid isomer is an active form of conjugated linoleic acid. See, particularly, page 185, the abstract. Regarding the limitation of the particularly amount of phosphatidyl residue, note as disclosed at page 11, line 13-25 in the specification, it is known that safflower oil contain about 0.4-1.0 % of phosphatidyl residue. It would have been reasonably expected that isomerized Safflower oil (also is the starting material herein) containing phosphatidyl residue. Cain et al. further teaches a CLA composition made from sunflower oil for food additive contains 48.9 % of c9, t11, 51.1 % of t10,

Art Unit: 1617

c12 linoleic acid or their esters. See, particularly, examples 6 at page 16, and example 18 at page 36, and claim 7. The composition is suitable for food products. See, particularly, claim 14.

Therefore it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a conjugated linoleic alkyl ester mixture from sunflower oil or safflower oil comprising c9, t11- and t10, c12-octadecadienoic moieties without/or with less than 2% of 8,10- and 11,13- octadecadienoic ester, such as those disclosed by Cain et al., and employ the mixture in food products.

A person of ordinary skill in the art would have been motivated to make a conjugated linoleic alkyl ester mixture from sunflower oil or safflower oil comprising c9, t11- and t10, c12-octadecadienoic moieties without/or with less than 2% of 8,10- and 11,13- octadecadienoic ester and employ the mixture in food products because 8,10- and 11,13- octadecadienoic esters are known not to be required in the active form of conjugated linoleic acid and the c9, t11 and t10, c12 isomers are known to be the preferred isomers in food products. Further, alkyl ester of c9, t11- and t10, c12-octadecadienoic acids are known to be similarly useful as the free acid and the other esters. Further, Baltes et al. teach that employment of low alkali alcoholate as catalysts for isomerization of unconjugated polyethenoid fatty acid compounds to conjugated isomers is known. See, column 2, lines 16-35, column 5, lines 5-21, column 8, lines 22-67, and the claims. Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made, to obtain conjugated linoleic acid from safflower oil through the isomerization process taught by Baltes.

Response to the Arguments

Applicants' remarks submitted May 6, 2003 have been fully considered, but are not persuasive for reasons discussed below.

5. As to the 1.132 declaration filed by the inventor, the examiner maintains his position stated in the office action mailed December 31, 2002 (paper No. 34): "the declaration fails to establish the fact that the conjugated linoleic acid disclosed by Cook or Cain as recited in the prior office action containing more than 2% of the isomers identified in the claim herein.

Particularly, applicant generated data, proffered to obviate prior art teachings, lacks the probative force accorded data generated by independent, disinterested parties. It is well settled patent law "that it is not a difficult matter to carry out a process in such a fashion that it will not be successful and, therefore, the failures of experimenters who have no interest in succeeding should not be accorded great weight" In re Michalek, 74 USPQ 108, at 109 citing Bullard Company et al v. Coe, 147 F.2d. 568, 64 USPQ 359." Applicants have argued that CLA compounds, including those disclosed in the cited prior art, inherently comprising more than 2% of trans, trans, 8, 10 and 11, 13 octadecadienoic acids or derivatives. The arguments are not convincing. Particularly, the presence of trans trans isomers is well known in the art, and is acknowledged by Cain (page 1, lines 15-25). However, Cain et al. do not disclose the presence of trans isomers in their CLA composition. The examiner is not convinced by the assumption that Cain et al. cannot detect the trans trans isomers, or simply ignore the presence of the isomers. The evidence provided with the declaration has been fully evaluated against the cited reference. Applicants provided results contrary to the references, making assumption without factual support. The examiner has not stated (and does not intend to) that applicants committed fraud.

Art Unit: 1617

The examiner merely states that the evidence are not convincing. Applicants' experiments provide a results contrary to those disclosed in the prior art is not convincing.

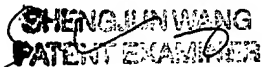
6. Applicants argued that the cited reference do not provide a reasonable expectation of success in making a CLA with less than 2% of trans trans, 8, 10, and 11, 13 isomers. These arguments are not probative. As discussed above, there is no sufficient evidence to disprove validity of the data disclosed by Cain et al. Further, the method to produce the CLA composition herein is old and well known. See Balter et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner



Shengjun Wang

July 18, 2003